

## PATENT COOPERATION TREATY

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## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference SALTERP47APCP1	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US04/24291	International filing date (day/month/year) 27 July 2004 (27.07.2004)	Priority date (day/month/year) 28 July 2003 (28.07.2003)
International Patent Classification (IPC) or national classification and IPC IPC: A61M 15/08( 2006.01) USPC: 128/207.18,206.11,203.22		
Applicant SALTER LABS		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of \_\_\_ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of report with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 04 March 2005 (04.03.2005)	Date of completion of this report 19 May 2007 (19.05.2007)
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/ US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer Justine Yu <i>J. Yu</i> Telephone No. 571-727-3700

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US04/24291

## I. Basis of the report

1. With regard to the **elements** of the international application:\*

☒ the international application as originally filed.

☒ the description:

pages 1-33 \_\_\_\_\_ as originally filed

pages NONE \_\_\_\_\_, filed with the demand: \*

pages NONE \_\_\_\_\_, filed with the letter of \_\_\_\_\_.

☒ the claims:

pages 34-41 \_\_\_\_\_, as originally filed

pages NONE \_\_\_\_\_, as amended (together with any statement) under Article 19

pages NONE \_\_\_\_\_, filed with the demand

pages NONE \_\_\_\_\_, filed with the letter of \_\_\_\_\_.

☒ the drawings:

pages 1-16 \_\_\_\_\_, as originally filed

pages NONE \_\_\_\_\_, filed with the demand

pages NONE \_\_\_\_\_, filed with the letter of \_\_\_\_\_.

☐ the sequence listing part of the description:

pages NONE \_\_\_\_\_, as originally filed

pages NONE \_\_\_\_\_, filed with the demand

pages NONE \_\_\_\_\_, filed with the letter of \_\_\_\_\_.

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in printed form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages NONE

☐ the claims, Nos. NONE

☐ the drawings, sheets/fig NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.  
PCT/US04/24291

## V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

### 1. STATEMENT

Novelty (N)	Claims <u>3,7,10,13,17,21-28,30,and 32-43</u>	YES
	Claims <u>1,2,4-6,8-9,11,12,14-16,18-20,29,and 31</u>	NO
Inventive Step (IS)	Claims <u>NONE</u>	YES
	Claims <u>1-43</u>	NO
Industrial Applicability (IA)	Claims <u>1-43</u>	YES
	Claims <u>NONE</u>	NO

### 2. CITATIONS AND EXPLANATIONS

Claims 1,2,4-6,8-9,11,12,14-16,18-20,29, and 31 lack novelty under PCT Article 33(2) as being anticipated by Payton US 4,660,555.

In figures 10-12, Payton discloses a nasal cannula for supplying a respiratory gas to a patient. The nasal cannula comprises a pair of supply lines (see abstract) each having a head at one end thereof with a discharge opening (20a) therein for discharging a respiratory gas. The opposite end of each of the pair supply lines is connected to a respiratory gas source (41). Each head is sized to be snugly received and retained within one of the nasal cavities of the patient (fig.1) while forming at least one leakage passage having a cross sectional open area (see fig.1) to maintain a sufficient positive back pressure in the patient during breathing. Payton in figure 10-12 continues to disclose that the exterior surface of the head has a plurality of elongated troughs (45) formed therein for partially defining a plurality of leakage passages therein to facilitate exhausting of any excess respiratory gas and inhalation of any room air required by the patient (see col.6 lines 45-51).

Claims 3,7,10,13,17,21-28,30, and 32-43 lack an inventive step under PCT Article 33(3) as being obvious over Payton US 4,660,555 in view of Hickie et al. 2002/0017300.

Payton discloses the claimed invention as applied for claims 1,2,4-6,8-9,11,12,14-16,18-20,29, and 31. Payton however does not disclose depicting between six and eight elongated troughs, a heater for heating the respiratory gas, a humidifier for supplying humidity of the respiratory gas and a pressure sensor. However, Hickie, which also relates to a nasal cannula, teaches that it was known at the time of the present invention to incorporate a heater, a humidifier and a pressure sensor for providing effective ventilator monitoring (paragraph 0012). Regarding the limitation of between six and eight elongated troughs, this limitation would have been obvious to one of ordinary skill in the art given the fact that Payton specifically discloses four troughs.

Claims 1-43 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.